



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

December 20, 2019

MEMORANDUM

SUBJECT: Semiannual Facility Inspection Report For:
Duluth, MN Animal Care and Use Program
Gulf Breeze, FL Animal Care and Use Program
Narragansett, RI Animal Care and Use Program

FROM: **Exemption 6** Director, Animal Resources and Research Support

THRU: Jim Harvey, Chairman, ORD Ecology IACUC *J Harvey*

TO: Wayne Cascio, Institutional Official, ORD Ecology IACUC

Exemption 6
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The semi-annual facility inspections for the ORD Animal Care and Use Programs in Duluth, Gulf Breeze and Narragansett were conducted in November and December of 2019 (specific dates are on the attached check lists). The facilities that house animals or support their care and maintenance were reviewed. The inspection teams consisted of at least two and usually 4 Ecology IACUC members at each location. Animal care and facilities staff also participated in the inspection in Duluth and Narragansett.

This summary report was prepared by **Exemption 6**. Findings for each location were reviewed on the day of inspection by the IACUC members. The participating members approved the evaluation. There were no minority views regarding the semiannual facility report.

The following facilities were inspected:

- Aquatics facilities including
 - Husbandry areas
 - Food storage
 - Exposure areas
 - Maintenance and support areas

Some questions were raised during the Duluth inspection that were addressed after the inspection was complete. These questions illuminated a significant deficiency in the program, and an adverse event with significant animal welfare issues. During the inspection it was noted that a box of dead animals was held in a freezer. These animals were open to the freezer environment, and the open box was located between two feed sources for the Duluth animals. During the review, the practice of holding deceased animals in space contiguous with food stock was discussed, and this unsanitary practice was going to be addressed.

(Food and deceased animals are no longer held in the same freezer.) The source of dead animals was addressed post inspection via email.

During the inspection, Duluth animal care personnel expressed concern about an uninterruptable power supply (UPS) that had failed over the weekend, impacting their aquatic environment management system. This failure was brought to the attention of the IACUC members, and animal care staff asked for some assistance making sure the aquatic environment wasn't impacted by the UPS again.

Email exchange following the visit highlighted the need for correction to the UPS/aquatic management system and brought to light issues on reporting adverse events to the IACUC and veterinary staff.

On Sunday, 11/3/19, the UPS system powering the controls for the aquatic management system failed. Water from Lake Superior began to enter the aquatic environment without appropriate conditioning at 7:03 AM and continued until the problem was resolved at 10:30 AM. This adverse event resulted in the mortality of approximately 30 *Xenopus tropicalis* adult frogs, 2 *tropicalis* tadpoles, 12 adult zebrafish, and 6 fathead minnow adults. This mortality was reported to the local IACUC representative on Monday 11/2/19, but not reported to the veterinary staff.

Changes have been made to the method of reporting of animal mortalities at this facility. The veterinary staff will now be promptly informed, and the Ecology IACUC will be updated on adverse events.

Changes have also been made to how the UPS and aquatic environment system are monitored. Additionally, the issue of the UPS has been elevated in importance and brought to the attention of ORM's Special Research Resources group. A replacement UPS is being sought.

Beyond the UPS failure, the facilities were largely in conformance with the US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, and the *Guide for the Care and Use of Laboratory Animals* (8th Edition) and applicable animal welfare regulations. See the attached table for a detailed listing of the deficiencies and their status regarding correction.



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December 20, 2019

MEMORANDUM

SUBJECT: Semiannual Ecology IACUC Animal Program Review Report

FROM: **Exemption 6** Director, Animal Resources and Research Support

THRU: Jim Harvey, Chairman, ORD Ecology IACUC 
Exemption 6 AED IACUC Member, ORD Ecology IACUC

TO: Wayne Cascio, Institutional Official, ORD Ecology IACUC

Evaluation of the Animal Care and Use Program

The Atlantic Ecology Division completed their first semiannual animal care and use program review on July 3, 2019, in accordance with the 8th edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*, recommendations from the Office of Laboratory Animal Welfare, requirements of the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, and, as applicable, 9CFR Chapter I, 2.31.

The following IACUC members participated in the review: Ecology IACUC Member; **Exemption 6** IACUC Administrator, and **Exemption 6** Director, Animal Resources Program Office. **Exemption 6** AED Associate Director, and **Exemption 6** AED Branch Chief, also attended.

This summary report was prepared by **Exemption 6**. Findings were reviewed by the IACUC members on July 3, 2019. The participating members approved the evaluation. There were no minority views regarding the semiannual program review. (Checklist attached)

The program review was performed following the formation of the Ecology IACUC, which was formalized 2 days before this program review. On July 1, 2019, a new IACUC covering three Ecology Divisions -- The Atlantic Ecology Division (AED), the Gulf Ecology Division, (GED) and the Midcontinent Ecology Division (following October 1, 2019, to be named the Great Lakes Ecology Division (GLED)) -- was formalized. This new IACUC, titled the Ecology IACUC,

comprehensively covers the 3 ecology divisions and brings all three into full regulatory compliance for IACUC composition and oversight. Prior to July 1, each Division had been following widely varying processes to handle animal research requirements. Work beginning July 1 will harmonize the practices across Divisions and bring all Divisions into full regulatory compliance.

There were no significant deficiencies endangering animal welfare noted during program review due to the expected functions of the Ecology IACUC. There were a number of minor deficiencies, and a large number of changes, again, noted due to the expected implementation of the Ecology IACUC.

Highlights of these changes include:

- Provision of veterinary oversight via the consultation and expertise of the RTP Attending Veterinarian.
- Formation of a properly constituted IACUC with all required roles filled, including Attending Veterinarian and Unaffiliated Member.
 - These two IACUC members are provided by shared resources with the RTP Animal Care and Uses Program.
 - AED will contribute two voting members to the new Ecology IACUC
- New orientation and training for IACUC members so they may better understand their new roles and responsibilities.
- The performance of the very first ever program review for AED.
- Instituting new methods for reporting animal welfare concerns, including the adoption of an anonymous hotline shared with the RTP Animal Care and Use Program.
- Introduction of the concept of animal care and use protocols and subsequent IACUC review to the AED management and IACUC members, and provision of examples of blank protocol forms.
 - Written animal care and use protocol requirements will be rolled out to the AED scientific staff using vertebrate animals when a suitable form is constructed, estimated to be early September.

With the application of the changes brought by the Ecology IACUC, the committee members found the animal program to either already be consistent with the Government Principles, the *Guide*, and applicable Animal Welfare Regulations or to be moving into compliance with these requirements as the Ecology IACUC settles into place and begins working.

Attachments

Duluth

Semiannual Program Review and Facility Inspection Checklist

About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), section [IV.B.1.-2.](#), requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the *Guide for the Care and Use of Laboratory Animals: Eighth Edition* ([Guide](#)) as a basis for evaluation.

How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
 - Institutional Policies and Responsibilities
 - Veterinary Care
- II. Semiannual Facility Inspection Checklist
 - Terrestrial Animal Housing and Support Areas
 - Aquatic Animal Housing and Support Areas
 - Cagewash
 - Special Facilities: Aseptic Surgery
 - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities: GLTED

Date: 11/6/2019

1. Animal Care and Use Program ^{NEW}		A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (<i>Guide, p 1</i>) [must]		X				
• IO has authority to allocate needed resources (<i>Guide, p 13</i>)		X				
• Resources necessary to manage program of veterinary care are provided (<i>Guide, p 14</i>) [must]		X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide, pp 11, 15</i>)		X				
• Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide, p 13</i>)		X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide, p 14</i>) [must]		X				
• Inter-institutional collaborations are described in formal written agreements (<i>Guide, p 15</i>)		X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide, p 15</i>)		X				
2. Disaster Planning and Emergency Preparedness ^{NEW}		A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (<i>Guide, p 35, p 75</i>) [must]					X	
• Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must]					X	
• Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>)					X	
• Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>)					X	
• Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>)					X	
• Plans include essential personnel and their training (<i>Guide, p 35</i>)					X	
• Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>)					X	
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>)		X				
3. IACUC ^{NEW}		A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must]		X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 26</i>) [must]		X				
• Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>)		X				
• IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>)					X	
4. IACUC Protocol Review - Special Considerations		A*	M	S	C	NA
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>)		X				
• For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>)		X				
• For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>)		X				
• Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must]						X
• Alternatives to physical restraint are considered (<i>Guide, p 29</i>)						X

- Period of restraint is the minimum to meet scientific objectives (*Guide*, [p 29](#))
- Training of animals to adapt to restraint is provided (*Guide*, [p 29](#))
- Animals that fail to adapt are removed from study (*Guide*, [p 29](#))
- Appropriate observation intervals of restrained animals are provided (*Guide*, [p 29](#))
- Veterinary care is provided if lesions or illness result from restraint (*Guide*, [p 30](#))
- **must** Explanations of purpose and duration of restraint are provided to study personnel (*Guide*, [p 30](#))
- Multiple surgical procedures on a single animal are justified and outcomes evaluated (*Guide*, [p 30](#))
- Major versus minor surgical procedures are evaluated on a case-by-case basis (*Guide*, [p 30](#))
- Multiple survival procedure justifications in non-regulated species conform to regulated species standards (*Guide*, [p 30](#))
- Animals on food/fluid restriction are monitored to ensure nutritional needs are met (*Guide*, [p 31](#))
- Body weights for food/fluid restricted animals are recorded at least weekly (*Guide*, [p 31](#))
- Daily written records are maintained for food/fluid restricted animals (*Guide*, [p 31](#))
- Pharmaceutical grade chemicals are used , when available, for animal-related procedures (*Guide*, [p 31](#))
- Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (*Guide*, [p 31](#))
- Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (*Guide*, [p 32](#))
- Disposition plans are considered for species removed from the wild (*Guide*, [p 32](#))
- Toe-clipping only used when no alternative, performed aseptically and with pain relief (*Guide*, [p 75](#))

5. IACUC Membership and Functions

- IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, [IV.A.3.](#))
- Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, [p 24](#))ⁱⁱ
- IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, [p 14](#))
- IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, [IV.B.](#))
- Conducts semiannual inspections of institutional animal facilities (PHS Policy, [IV.B.](#))
- IACUC organizationally reports to the Institutional Official (PHS Policy, [IV.A.1.b.](#))
- Methods for reporting and investigating animal welfare concerns are in place (*Guide*, [p 23](#)) **[must]**
- Reviews and investigates concerns about animal care and use at institutionⁱⁱⁱ (PHS Policy, [IV.B.](#))
- Procedures are in place for review, approval, and suspension of animal activities^{iv} (PHS Policy, [IV.B.](#))
- Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, [IV.B.](#))
- Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (*Guide*, [p 27-32](#))
- Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS^v (*Guide*, [p 30](#)) **[must]**

6. IACUC Training NEW

- All IACUC members should receive:
 - Formal orientation to institution's program (*Guide*, p 17)

<ul style="list-style-type: none"> ○ Training on legislation, regulations, guidelines, and policies (<i>Guide</i>, p 17) ○ Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide</i>, p 17) ○ Training on how to review protocols as well as evaluate the program (<i>Guide</i>, p 17) ○ Ongoing training/education (<i>Guide</i>, p 17) 	X					
	X					
	X					
	X					
7. IACUC Records and Reporting Requirements^{vi}	A*	M	S	C	NA	
<ul style="list-style-type: none"> • Semiannual report to the IO (PHS Policy, IV.B.) 	X					
<ul style="list-style-type: none"> ○ Submitted to IO every 6 months ○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies) 	X					
<ul style="list-style-type: none"> ○ Includes minority IACUC views ○ Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure^{vii} 	X					X
<ul style="list-style-type: none"> ○ Distinguishes significant from minor deficiencies 	X					
<ul style="list-style-type: none"> ○ Includes a plan and schedule for correction for each deficiency identified^{viii} <ul style="list-style-type: none"> • Reports to OLAW (PHS Policy, IV.F.) 	X					
<ul style="list-style-type: none"> ○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views ○ Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034) ○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034) 	X					X
<ul style="list-style-type: none"> ○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034) 						X
<ul style="list-style-type: none"> • Reports to U.S. Department of Agriculture (USDA) or Federal funding agency^{ix} <ul style="list-style-type: none"> ○ Annual report to USDA contains required information including all exceptions/exemptions ○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards ○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies ○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency 						X
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<ul style="list-style-type: none"> ○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency 						X
<ul style="list-style-type: none"> • Records (PHS Policy, IV.E.) <ul style="list-style-type: none"> ○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years ○ Records of IACUC reviews of animal activities include all required information^x ○ Records of IACUC reviews are maintained for 3 years after the completion of the study 						X
						X
						X
						X
8. Veterinary Care (See also next section - Veterinary Care)	A*	M	S	C	NA	
<ul style="list-style-type: none"> • An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care^{xi} 	X					
<ul style="list-style-type: none"> • Veterinary access to all animals is provided (<i>Guide</i>, p 14) [must] 	X					
<ul style="list-style-type: none"> • Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide</i>, p 14) [must] 	X					
<ul style="list-style-type: none"> • Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide</i>, p 5) [must] • Veterinarian provides consultation when interventional control is not possible (<i>Guide</i>, p 5) [must] 	X					
<ul style="list-style-type: none"> • Veterinarian provides consultation when interventional control is not possible (<i>Guide</i>, p 5) [must] 	X					
<ul style="list-style-type: none"> • If part time /consulting veterinarian, visits meet programmatic needs (<i>Guide</i>, p 14) • Regular communication occurs between veterinarian and IACUC (<i>Guide</i>, p 14) • Veterinarian(s) have experience and training in species used (<i>Guide</i>, p 15) [must] • Veterinarian(s) have experience in facility administration/management (<i>Guide</i>, p 15) 	X					
<ul style="list-style-type: none"> • If part time /consulting veterinarian, visits meet programmatic needs (<i>Guide</i>, p 14) • Regular communication occurs between veterinarian and IACUC (<i>Guide</i>, p 14) • Veterinarian(s) have experience and training in species used (<i>Guide</i>, p 15) [must] • Veterinarian(s) have experience in facility administration/management (<i>Guide</i>, p 15) 	X					
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<ul style="list-style-type: none"> • Veterinarian(s) have experience and training in species used (<i>Guide</i>, p 15) [must] • Veterinarian(s) have experience in facility administration/management (<i>Guide</i>, p 15) 	X					
<ul style="list-style-type: none"> • Veterinarian(s) have experience in facility administration/management (<i>Guide</i>, p 15) 	X					

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| | o Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide</i> , p 22) [must] | | | | | X |
| | o If serum samples are collected, the purpose is consistent with federal and state laws (<i>Guide</i> , p 22) [must] | | | | | X |
| | • Waste anesthetic gases are scavenged (<i>Guide</i> , p 21) | | | | | X |
| | • Hearing protection is provided in high noise areas (<i>Guide</i> , p 22) | X | | | | |
| | • Respiratory protection is available when performing airborne particulate work (<i>Guide</i> , p 22) | X | | | | |
| | • Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: | | | | | |
| | o Tuberculosis screening provided for all exposed personnel (<i>Guide</i> , p 23) | | | | | X |
| | o Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i> , p 23) | | | | | X |
| | o PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide</i> , p 21) | | | | | X |
| | o Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide</i> , p 23) | | | | | X |
| | • Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide</i> , p 32) | | | | | X |
| 11. | Personnel Security NEW | A* | M | S | C | NA |
| | • Preventive measures in place include pre-employment screening, and physical and IT security (<i>Guide</i> , p 23) | X | | | | |
| 12. | Investigating & Reporting Animal Welfare Concerns NEW | A* | M | S | C | NA |
| | • Methods for investigating and reporting animal welfare concerns are established (<i>Guide</i> , p 23) [must] | | | | | X |
| | • Reported concerns and corrective actions are documented (<i>Guide</i> , p 24) | | | | | X |
| | • Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (<i>Guide</i> , p 24) | | | | | X |
| | o Includes multiple contacts (<i>Guide</i> , p 24) | | | | | X |
| | o Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (<i>Guide</i> , p 24) | | | | | X |

Procedures are in place to address:					
Problems with experiments to determine course of treatment in consultation with investigator (Guide, p 114)	X				
Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (Guide, p 114)					X
Veterinary review and oversight of medical and animal use records (Guide, p 115)	X				
Procedures established for timely reporting of animal injury, illness, or disease (Guide, p 114) [must]	X				
Procedures established for veterinary assessment, treatment, or euthanasia (Guide, p 114) [must]	X				
Veterinarian is authorized to treat, relieve pain, and/or euthanize (Guide, p 114) [must]	X				

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	C	NA
Procedures for lawful animal procurement are in place (Guide, p 106) [must]	X				
Sufficient facilities and expertise are confirmed prior to procurement (Guide, p 106)	X				
Procurement is linked to IACUC review and approval (Guide, p 106)	X				
Random source dogs and cats are inspected for identification (Guide, p 106)					X
Population status of wildlife species is considered prior to procurement (Guide, p 106)	X				
Appropriate records are maintained on animal acquisition (Guide, p 106)	X				
Animal vendors are evaluated to meet program needs and quality (Guide, p 106)	X				
Breeding colonies are based on need and managed to minimize numbers (Guide, p 107)	X				
Procedures for compliance with animal transportation regulations, including international requirements, are in place (Guide, p 107) [must]	X				
Transportation is planned to ensure safety, security and minimize risk (Guide, p 107)	X				
Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (Guide, pp 107-108)	X				
Appropriate loading and unloading facilities are available (Guide, p 109)	X				
Environment at receiving site is appropriate (Guide, p 109)	X				
Policies in place on separation by species, source, and health status (Guide, pp 109, 111-112)	X				
Procedures in place for quarantine to include zoonoses prevention (Guide, p 110)					X
Quarantined animals from different shipments are handled separately or physically separated (Guide, p 110)	X				
Procedures in place for stabilization/acclimation (Guide, pp 110-111)	X				
Policies in place for isolation of sick animals (Guide, p 112)	X				
Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (Guide, p 112)	X				
Diagnostic resources are available for preventive health program (Guide, p 112)	X				

3. Surgery

	A*	M	S	C	NA
Surgical outcomes are assessed and corrective changes instituted (Guide, p 115)					X
Researchers have appropriate training to ensure good technique (Guide, p 115) [must]					X
Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (Guide, p 116)					X
Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (Guide, p 116)					X
Surgical procedures including laparoscopic procedures are categorized as major or minor (Guide, pp 117-118)					X
For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (Guide, p 118)					X

<ul style="list-style-type: none"> Aseptic technique is followed for survival surgical procedures (<i>Guide</i>, pp 118-119) Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (<i>Guide</i>, p 119) Procedures for monitoring surgical anesthesia and analgesia are in place (<i>Guide</i>, p 119) For aquatic species, skin surfaces are kept moist during surgical procedures (<i>Guide</i>, p 119) Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (<i>Guide</i>, pp 119-120) 										X
										X
										X
										X
										X
4. Pain, Distress, Anesthesia and Analgesia	A*	M	S	C	NA					
<ul style="list-style-type: none"> Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (<i>Guide</i>, p 121) Selection of analgesics and anesthetics is based on professional veterinary judgment (<i>Guide</i>, p 121) MS-222, Rapid chilling Painful procedures are monitored to ensure appropriate analgesic management (<i>Guide</i>, p 122) Nonpharmacologic control of pain is considered as an element of postprocedural care (<i>Guide</i>, p 122) Procedures are in place to assure antinociception before surgery begins (<i>Guide</i>, p 122) [must] Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (<i>Guide</i>, p 122) Special precautions for the use of paralytics are in place to ensure anesthesia^{xiv} (<i>Guide</i>, p 123) 	X									
	X									
	X									
										X
										X
										X
										X
5. Euthanasia	A*	M	S	C	NA					
<ul style="list-style-type: none"> Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (<i>Guide</i>, p 123) Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (<i>Guide</i>, pp 123-124) Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide</i>, p 124) Procedures and training are in place to ensure death is confirmed (<i>Guide</i>, p 124) [must] 	X									
	X									
	X									
	X									
6. Drug Storage and Control NEW	A*	M	S	C	NA					
<ul style="list-style-type: none"> Program complies with federal regulations for human and veterinary drugs(<i>Guide</i>, p 115) [must] Drug records and storage procedures are reviewed during facility inspections (<i>Guide</i>, p 115) Procedures are in place to ensure analgesics and anesthetics are used within expiration date (<i>Guide</i>, p 122) [must] Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (<i>Guide</i>, p 122) 	X									
	X									
	X									
	X									

* A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

II. Semiannual Facility Inspection Report

Date: 11/6/2019

Members in Attendance:

Exemption 6Exemption 6

Leslie Jarrell (via facetime),

Exemption 6

Deficiency Category*	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
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M	Rm 159	Several tanks with high density of Flat Head Minnows-thin fish into more tanks			
M	Rm 159	1 Large Single Housed Blue Gill Fish-multiple house			
M	Rm 159	Lab coat hanging on Fish Rack-remove lab coat and store in another room			
M	Rm 159	Rusty Razor Blade-dispose of razor blade			
M	Rm 159	Wood in the room- replace with plastic			
M	Rm 159	Particle board clipboards-replace with plastic clipboards			
M	Rm 160	Several tanks with high density of Flat Head Minnows-thin fish into more tanks			
M	Rm 160	Oxygen Tank needs to be more secured to rack			
M	Rm 160	Rusty Razor Blade-dispose of razor blade			
M	Rm 162	Lab coat hanging on Fish Rack-remove lab coat and store in another room			
M	Rm 162	Broken 5G Tank-remove broken tank			
M	Rm 163	Freezers, paint is peeling off and rusty-replace freezers			
M	Rm 163	Storage of unbagged carcasses with food-bag carcasses and store food in another freezer			
M	Rm 166	Electric junction box setting on rack with water pump-attach electric junction box to wall			
M	Rm 166	Wood in room-replace with plastic			
M	Rm 167	Wood in room-replace with plastic			
M	Rm 167	Particle board clipboards-replace with plastic clipboards			

M	Rm 167	Bleach container-do not keep in room
M	Rm 167	Broken Trash can-replace with another trash can
M	Rm 167	Cardboard box on floor-remove cardboard from the room
M	Rm 167	Items on the floor-remove items as they are trip hazards
M	Rm 167	Drain covers in sink- store these closer to the drains
M	Rm 167	GFCI Protected Outlets-make sure these are really GFI
M	Rm 168	Stir plate sitting on wood-remove wood, replace with plastic
M	Rm 168	Furniture mover is wood, remove mover from this room
M	Rm 168	Particle board clipboards-replace with plastic clipboards
M	Rm 168	Electric junction box setting on rack with water pump-attach electric junction box to wall
M	Rm 169	Cardboard on top of racks-remove and replace with plastic
M		UV light, unit states failure-fix sensor
M		Light levels in room with Albino frogs-need to detect levels as Albino frogs are more sensitive to light
M		Body conditioning of Zebrafish-learn how to score on body condition
M		Liquid chemicals in rooms on high shelves-move liquid chemicals to lower shelf
M		Metal chair with wooden top-remove chair from room

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NA = not applicable

✓ Check if repeat deficiency

III. Endnotes

ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

ⁱⁱ Part 2 Subpart C - Research Facilities

- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

ⁱⁱⁱ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

^{iv} 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

^v 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

^{vi} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{vii} 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

^{viii} 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

^{ix} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:
- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - “No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing...”

^{xi} 2.33(a)(1) - “In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.” [USDA requirement additional]

^{xii} 2.32(c) - “Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures.”

^{xiii} 2.32(c) - additional specifications include:

- “proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility”
- “methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility...”
- “utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act.” [USDA training specifications are more detailed than PHS Policy].

^{xiv} 2.31(d)(iv)(C) - “Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”

Semiannual Program Review and Facility Inspection Checklist

About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), section [IV.B.1.-2.](#), requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the *Guide for the Care and Use of Laboratory Animals: Eighth Edition ([Guide](#))* as a basis for evaluation.

How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
 - Institutional Policies and Responsibilities
 - Veterinary Care
- II. Semiannual Facility Inspection Checklist
 - Terrestrial Animal Housing and Support Areas
 - Aquatic Animal Housing and Support Areas
 - Cagewash
 - Special Facilities: Aseptic Surgery
 - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

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Questions or comments?

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I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities: Gulf Breeze

Date: 11/21/2019

		A*	M	S	C	NA
1. Animal Care and Use Program ^{NEW}						
• Responsibility for animal well-being is assumed by all members of the program (<i>Guide, p 1</i>) [must]		X				
• IO has authority to allocate needed resources (<i>Guide, p 13</i>)		X				
• Resources necessary to manage program of veterinary care are provided (<i>Guide, p 14</i>) [must]		X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide, pp 11, 15</i>)		X				
• Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide, p 13</i>)		X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide, p 14</i>) [must]		X				
• Inter-institutional collaborations are described in formal written agreements (<i>Guide, p 15</i>)						X
• Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide, p 15</i>)						X
2. Disaster Planning and Emergency Preparedness ^{NEW}		A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (<i>Guide, p 35, p 75</i>) [must]		X				
• Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must]		X				
• Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>)						X
• Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>)		X				
• Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>)						X
• Plans include essential personnel and their training (<i>Guide, p 35</i>)		X				
• Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>)		X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>)		X				
3. IACUC ^{NEW}		A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must]		X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 26</i>) [must]		X				
• Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>)		X				
• IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>)		X				
4. IACUC Protocol Review - Special Considerations		A*	M	S	C	NA
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>)		X				
• For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>)						X
• For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>)						X
• Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must]						X
• Alternatives to physical restraint are considered (<i>Guide, p 29</i>)						X
• Period of restraint is the minimum to meet scientific objectives (<i>Guide, p 29</i>)						X
• Training of animals to adapt to restraint is provided (<i>Guide, p 29</i>)						X

○ Ongoing training/education (<i>Guide</i> , p 17)	X				
7. IACUC Records and Reporting Requirements^{vi}	A*	M	S	C	NA
• Semiannual report to the IO (PHS Policy, IV.B.)	X				
○ Submitted to IO every 6 months	X				
○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
○ Includes minority IACUC views	X				
○ Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ^{vii}					X
○ Distinguishes significant from minor deficiencies	X				
○ Includes a plan and schedule for correction for each deficiency identified ^{viii}	X				
• Reports to OLAW (PHS Policy, IV.F.)					
○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views					X
○ Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034)					X
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)					X
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency ^{ix}					
○ Annual report to USDA contains required information including all exceptions/exemptions					X
○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards					X
○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies					X
○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency					X
• Records (PHS Policy, IV.E.)					
○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X				
○ Records of IACUC reviews of animal activities include all required information ^x	X				
○ Records of IACUC reviews are maintained for 3 years after the completion of the study	X				
8. Veterinary Care (See also next section - Veterinary Care)	A*	M	S	C	NA
• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care ^{xi}		X			
• Veterinary access to all animals is provided (<i>Guide</i> , p 14) [must]		X			
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide</i> , p 14) [must]		X			
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide</i> , p 5) [must]	X				
• Veterinarian provides consultation when interventional control is not possible (<i>Guide</i> , p 5) [must]	X				
• If part time /consulting veterinarian, visits meet programmatic needs (<i>Guide</i> , p 14)	X				
• Regular communication occurs between veterinarian and IACUC (<i>Guide</i> , p 14)	X				
• Veterinarian(s) have experience and training in species used (<i>Guide</i> , p 15) [must]	X				
• Veterinarian(s) have experience in facility administration/management (<i>Guide</i> , p 15)	X				
9. Personnel Qualifications and Training	A*	M	S	C	NA
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]					
○ Veterinary/other professional staff (<i>Guide</i> , p 15-16)	X				
○ IACUC members (<i>Guide</i> , p 17)	X				
○ Animal care personnel (<i>Guide</i> , p 16)					X

<ul style="list-style-type: none"> ○ Research investigators, instructors, technicians, trainees, and students (<i>Guide</i>, pp 16-17) 	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide</i> , pp 16-17)	X				
• Training is available prior to starting animal activity (<i>Guide</i> , p 17)	X				
• Training is documented (<i>Guide</i> , p 15)	X				
• Training program content includes: (<i>Guide</i> , p 17)					
○ Methods for reporting concerns (<i>Guide</i> , p 17)	X				
○ Humane practices of animal care (e.g., housing, husbandry, handling) ^{xii}	X				
○ Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide</i> , p 17) ^{xiii}	X				
○ Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	X				
○ Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	X				
○ Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (<i>Guide</i> , p 20)					X
○ Animal care and use legislation (<i>Guide</i> , p 17)	X				
○ IACUC function (<i>Guide</i> , p 17)	X				
○ Ethics of animal use and Three R's (<i>Guide</i> , p 17)	X				
10. Occupational Health and Safety of Personnel	A*	M	S	C	NA
• Program is in place and is consistent with federal, state, and local regulations (<i>Guide</i> , p 17) [must]	X				
• Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide</i> , p 18)	X				
• Changing, washing, and showering facilities are available as appropriate (<i>Guide</i> , p 19)	X				
• Hazardous facilities are separated from other areas and identified as limited access (<i>Guide</i> , p 19)	X				
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide</i> , p 20)	X				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide</i> , p 20)	X				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , p 21)	X				
• Personal Protective Equipment for the work area is appropriate and available (<i>Guide</i> , p 21)	X				
• Program for medical evaluation and preventive medicine for personnel includes:					
○ Pre-employment evaluation including health history (<i>Guide</i> , p 22)					X
○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (<i>Guide</i> , p 22)	X				
○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (<i>Guide</i> , p 23)	X				
○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (<i>Guide</i> , p 23)	X				
○ Promotes early diagnosis of allergies including preexisting conditions (<i>Guide</i> , p 22)					X
○ Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide</i> , p 22) [must]					X
○ If serum samples are collected, the purpose is consistent with federal and state laws (<i>Guide</i> , p 22) [must]	X				
• Waste anesthetic gases are scavenged (<i>Guide</i> , p 21)					X
• Hearing protection is provided in high noise areas (<i>Guide</i> , p 22)	X				
• Respiratory protection is available when performing airborne particulate work (<i>Guide</i> , p 22)					X
• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					

	A	M	S	C	NA
<ul style="list-style-type: none"> ○ Tuberculosis screening provided for all exposed personnel (<i>Guide</i>, p 23) ○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i>, p 23) ○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide</i>, p 21) ○ Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide</i>, p 23) • Occupational safety and health of field studies is reviewed by OSH committee or office (<i>Guide</i>, p 32) 	X				
11. Personnel Security NEW	A*	M	S	C	NA
<ul style="list-style-type: none"> • Preventive measures in place include pre-employment screening, and physical and IT security (<i>Guide</i>, p 23) 	X				
12. Investigating & Reporting Animal Welfare Concerns NEW	A*	M	S	C	NA
<ul style="list-style-type: none"> • Methods for investigating and reporting animal welfare concerns are established (<i>Guide</i>, p 23) [must] • Reported concerns and corrective actions are documented (<i>Guide</i>, p 24) • Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (<i>Guide</i>, p 24) <ul style="list-style-type: none"> ○ Includes multiple contacts (<i>Guide</i>, p 24) ○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (<i>Guide</i>, p 24) 	X				
	X				
	X				
	X				
	X				

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NA = not applicable

Veterinary Care

Date: 11/21/2019

1. Clinical Care and Management NEW

	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (<i>Guide, p 105</i>) [must]	X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (<i>Guide, p 106</i>)	X				
• Veterinarian provides oversight to surgery and perioperative care (<i>Guide, p 106</i>)					X
• Veterinary care program is appropriate for program requirements (<i>Guide, pp 113-114</i>)		X			
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide, p 114</i>)	X				
• Procedures to triage and prioritize incident reports are in place (<i>Guide, p 114</i>)				X	
• Procedures are in place to address: <ul style="list-style-type: none"> Problems with experiments to determine course of treatment in consultation with investigator(<i>Guide, p 114</i>) Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (<i>Guide, p 114</i>) Veterinary review and oversight of medical and animal use records (<i>Guide, p 115</i>) 				X	
• Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide, p 114</i>) [must]				X	
• Procedures established for veterinary assessment, treatment, or euthanasia (<i>Guide, p 114</i>) [must]				X	
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (<i>Guide, p 114</i>) [must]				X	

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (<i>Guide, p 106</i>) [must]	X				
• Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide, p 106</i>)	X				
• Procurement is linked to IACUC review and approval (<i>Guide, p 106</i>)	X				
• Random source dogs and cats are inspected for identification (<i>Guide, p 106</i>)					X
• Population status of wildlife species is considered prior to procurement (<i>Guide, p 106</i>)	X				
• Appropriate records are maintained on animal acquisition (<i>Guide, p 106</i>)	X				
• Animal vendors are evaluated to meet program needs and quality (<i>Guide, p 106</i>)	X				
• Breeding colonies are based on need and managed to minimize numbers (<i>Guide, p 107</i>)	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (<i>Guide, p 107</i>) [must]	X				
• Transportation is planned to ensure safety, security and minimize risk (<i>Guide, p 107</i>)	X				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (<i>Guide, pp 107- 108</i>)	X				
• Appropriate loading and unloading facilities are available (<i>Guide, p 109</i>)	X				
• Environment at receiving site is appropriate (<i>Guide, p 109</i>)	X				
• Policies in place on separation by species, source, and health status (<i>Guide, pp 109, 111-112</i>)	X				
• Procedures in place for quarantine to include zoonoses prevention (<i>Guide, p 110</i>)	X				
• Quarantined animals from different shipments are handled separately or physically separated (<i>Guide, p 110</i>)	X				
• Procedures in place for stabilization/acclimation (<i>Guide, pp 110-111</i>)	X				
• Policies in place for isolation of sick animals (<i>Guide, p 112</i>)					X
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (<i>Guide, p 112</i>)	X				
• Diagnostic resources are available for preventive health program (<i>Guide, p 112</i>)				X	

3. Surgery

- Surgical outcomes are assessed and corrective changes instituted (*Guide, p 115*)
- Researchers have appropriate training to ensure good technique (*Guide, p 115*) **[must]**
- Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide, p 116*)
- Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide, p 116*)
- Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide, pp 117-118*)
- For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide, p 118*)
- Aseptic technique is followed for survival surgical procedures (*Guide, pp 118-119*)
- Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide, p 119*)
- Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide, p 119*)
- For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide, p 119*)
- Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (*Guide, pp 119-120*)

A*	M	S	C	NA
				X
				X
				X
				X
				X
				X
				X
				X
				X
				X
				X

4. Pain, Distress, Anesthesia and Analgesia

- Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (*Guide, p 121*)
- Selection of analgesics and anesthetics is based on professional veterinary judgment (*Guide, p 121*)
- Painful procedures are monitored to ensure appropriate analgesic management (*Guide, p 122*)
- Nonpharmacologic control of pain is considered as an element of postprocedural care (*Guide, p 122*)
- Procedures are in place to assure antinociception before surgery begins (*Guide, p 122*) **[must]**
- Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (*Guide, p 122*)
- Special precautions for the use of paralytics are in place to ensure anesthesia^{xiv} (*Guide, p 123*)

A*	M	S	C	NA
X				
				X
				X
				X
				X
				X
				X

5. Euthanasia

- Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide, p 123*)
- Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide, pp 123-124*)
- Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide, p 124*)
- Procedures and training are in place to ensure death is confirmed (*Guide, p 124*) **[must]**

A*	M	S	C	NA
X				
			X	
X				
X				

6. Drug Storage and Control ^{NEW}

- Program complies with federal regulations for human and veterinary drugs (*Guide, p 115*) **[must]**
- Drug records and storage procedures are reviewed during facility inspections (*Guide, p 115*)
- Procedures are in place to ensure analgesics and anesthetics are used within expiration date (*Guide, p 122*) **[must]**
- Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide, p 122*)

A*	M	S	C	NA
X				
X				
X				
X				

* A = acceptable
M = minor deficiency
Semiannual Checklist

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

II. Semiannual Facility Inspection Checklist

Terrestrial Animal Housing and Support Areas

Date: 11/21/2019

Location: GEMMD Wetlabs

A* M S C NA

• Location:					
○ animal areas separate from personnel areas (<i>Guide</i> , p 134)					X
○ separation of species (<i>Guide</i> , p 111)					X
○ separation by disease status (<i>Guide</i> , p 111)					X
○ security and access control (<i>Guide</i> , p 151)					X
• Construction:					
○ corridors (<i>Guide</i> , p 136)					X
○ animal room doors (<i>Guide</i> , p 137)					X
○ exterior windows (<i>Guide</i> , p 137)					X
○ floors (<i>Guide</i> , p 137)					X
○ drainage (<i>Guide</i> , p 138)					X
○ walls and ceilings (<i>Guide</i> , p 138)					X
○ heating ventilation and air conditioning (<i>Guide</i> , p 139)					X
○ power and lighting (<i>Guide</i> , p 141)					X
○ noise control (<i>Guide</i> , p 142)					X
○ vibration control (<i>Guide</i> , p 142)					X
○ environmental monitoring (<i>Guide</i> , p 143)					X
• Room/Cage:					
○ temperature and humidity (<i>Guide</i> , p 43)					X
○ ventilation and air quality (<i>Guide</i> , p 45)					X
○ illumination (<i>Guide</i> , p 47)					X
○ noise and vibration (<i>Guide</i> , p 49)					X
• Primary Enclosure:					
○ space meets physiologic, behavioral ^{xv} , and social ^{xvi} needs (<i>Guide</i> , pp 51, 55-63)					X
○ secure environment provided (<i>Guide</i> , p 51)					X
○ durable, nontoxic materials in good repair and no risk of injury (<i>Guide</i> , p 51)					X
○ flooring is safe and appropriate for species (<i>Guide</i> , p 51)					X
○ adequate bedding and structures for resting, sleeping, breeding (<i>Guide</i> , p 52)					X
○ objective assessments of housing and management are made (<i>Guide</i> , p 52)					X
○ procedures for routine husbandry are documented (<i>Guide</i> , p 52)					X
○ socially housed animals can escape or hide to avoid aggression (<i>Guide</i> , p 55)					X
○ cage height provides adequate clearance (<i>Guide</i> , p 56)					X
○ animals express natural postures, can turn around, access food and water, and rest away from urine and feces (<i>Guide</i> , p 56) [must]					X
○ rationale ^{xvii} for <i>Guide</i> /USDA space exceptions approved by IACUC and based on performance indices (<i>Guide</i> , p 56)					X
○ dogs and cats allowed to exercise and provided human interaction (<i>Guide</i> , p 58)					X
○ nonhuman primates are socially housed except for scientific, veterinary or					X

behavior reasons (<i>Guide</i> , pp 58-59)	
○ single housing of nonhuman primates is for shortest duration possible (<i>Guide</i> , p 60)	X
○ opportunities for release into larger enclosures is considered for single caged nonhuman primates (<i>Guide</i> , p 60)	X
○ agricultural animals are housed socially (<i>Guide</i> , p 60)	X
○ food troughs and water devices for agricultural animals allow access for all animals (<i>Guide</i> , p 60)	X
• Environmental Enrichment, Behavioral and Social Management:	
○ structures and resources promote species typical behavior (<i>Guide</i> , pp 52-54)	X
○ novelty of enrichment is considered (<i>Guide</i> , p 53)	X
○ species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian (<i>Guide</i> , pp 53, 58, 60, 63)	X
○ animal care personnel receive training to identify abnormal animal behaviors (<i>Guide</i> , p 53)	X
○ stability of pairs or groups is monitored for incompatibility (<i>Guide</i> , p 64)	X
○ single housing is justified for social species (<i>Guide</i> , p 64)	X
○ single housing is limited to the minimum period necessary (<i>Guide</i> , p 64)	X
○ additional enrichment for single housed animals is provided (<i>Guide</i> , p 64)	X
○ single housing is reviewed regularly by IACUC and veterinarian (<i>Guide</i> , p 64)	X
○ habituation to routine procedures is part of enrichment program (<i>Guide</i> , p 64)	X
• Sheltered or Outdoor Housing: (e.g., barns, corrals, pastures, islands)	
○ weather protection and opportunity for retreat (<i>Guide</i> , p 54) [must]	X
○ appropriate size (<i>Guide</i> , p 54)	X
○ ventilation and sanitation of shelter (no waste/moisture build-up) (<i>Guide</i> , p 54)	X
○ animal acclimation (<i>Guide</i> , p 55)	X
○ social compatibility (<i>Guide</i> , p 55)	X
○ roundup/restraint procedures (<i>Guide</i> , p 55)	X
○ appropriate security (<i>Guide</i> , p 55)	X
• Naturalistic Environments:	
○ animals added /removed with consideration of effect on group (<i>Guide</i> , p 55)	X
○ adequate food, fresh water, and shelter ensured (<i>Guide</i> , p 55)	X
• Food:	
○ feeding schedule and procedures including caloric intake management (<i>Guide</i> , pp 65-67)	X
○ contamination prevention (<i>Guide</i> , p 65)	X
○ vendor quality control (<i>Guide</i> , p 66)	X
○ storage in sealed containers (<i>Guide</i> , p 66)	X
○ expiration date labeling (<i>Guide</i> , p 66)	X
○ vermin control (<i>Guide</i> , p 66)	X
○ rotation of stocks (<i>Guide</i> , p 66)	X
• Water:	
○ ad libitum unless justified (<i>Guide</i> , pp 67-68)	X
○ QC procedures (<i>Guide</i> , pp 67-68)	X
• Bedding and Nesting Materials:	
○ species appropriate (<i>Guide</i> , pp 68-69)	X
○ keeps animals dry (<i>Guide</i> , pp 68-69)	X
○ QC procedures (<i>Guide</i> , pp 68-69)	X
○ minimizes scientific variables (<i>Guide</i> , pp 68-69)	X
• Sanitation:	

○ frequency of bedding/substrate change (<i>Guide</i> , p 70)	X
○ cleaning and disinfection of microenvironment (<i>Guide</i> , pp 70-71)	X
○ cleaning and disinfection of macroenvironment (<i>Guide</i> , p 72)	X
○ assessing effectiveness (<i>Guide</i> , p 73)	X
• Waste Disposal:	
○ procedures for collection (<i>Guide</i> , pp 73-74)	X
○ procedures for storage and disposal (<i>Guide</i> , pp 73-74)	X
○ hazardous wastes are rendered safe before removal from facility (<i>Guide</i> , pp 73-74) [must]	X
○ animal carcasses (<i>Guide</i> , pp 73-74)	X
• Pest Control:	
○ regularly scheduled (<i>Guide</i> , p 74)	X
○ documented program including control of rodent pests and insecticide use (<i>Guide</i> , p 74)	X
• Emergency, Weekend, and Holiday Animal Care:	
○ care provided by qualified personnel every day (<i>Guide</i> , p 74)	X
○ provision for accessible contact information (<i>Guide</i> , p 74)	X
○ monitoring of backup systems (<i>Guide</i> , p 143)	X
○ veterinary care available after hours, weekends, and holidays (<i>Guide</i> , pp 74, 114) [must]	X
○ a disaster plan that takes into account both personnel and animals (<i>Guide</i> , p 75)	X
• Identification:	
○ cage/rack cards contain required information (<i>Guide</i> , p 75)	X
○ genotype information included and standardized nomenclature used when applicable (<i>Guide</i> , p 75)	X
• Recordkeeping:	
○ clinical records accessible and contain appropriate information (<i>Guide</i> , pp 75-76)	X
○ records are provided when animals are transferred between institutions (<i>Guide</i> , p 75)	X
• Breeding Genetics and Nomenclature:	
○ appropriate genetic records, management and monitoring procedures (<i>Guide</i> , p 76)	X
○ phenotypes that affect wellbeing are reported to IACUC and effectively managed (<i>Guide</i> , p 77)	X
• Storage:	
○ adequate space for equipment, supplies, food, bedding and refuse (<i>Guide</i> , p 141)	X
○ bedding in vermin-free area and protected from contamination(<i>Guide</i> , p 141)	X
○ food in vermin-free, temperature and humidity controlled area and protected from contamination (<i>Guide</i> , p 141)	X
○ refuse storage is separate (<i>Guide</i> , p 141)	X
○ carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (<i>Guide</i> , p 141)	X
• Personnel:	
○ adequate space for locker rooms, administration and training (<i>Guide</i> , p 135)	X
* A = acceptable	
M = minor deficiency	
S = significant deficiency (is or may be a threat to animal health or safety)	
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)	
NA = not applicable	

NOTES:

Aquatic Animal Housing and Support Areas NEW

Date: 11/21/2019

Location: GEMMD Wetlabs

	A*	M	S	C	NA
• Location:					
○ animal areas separate from personnel areas (<i>Guide</i> , p 134)	X				
○ separation of species (<i>Guide</i> , p 111)	X				
○ separation by disease status (<i>Guide</i> , p 111)	X				
○ security and access control (<i>Guide</i> , p 151)	X				
• Construction:					
○ corridors (<i>Guide</i> , p 136)					X
○ animal room doors (<i>Guide</i> , pp 137, 150)					X
○ exterior windows (<i>Guide</i> , p 137)					X
○ floors (<i>Guide</i> , pp 137, 150)	X				
○ drainage (<i>Guide</i> , pp 138, 150)	X				
○ walls and ceilings (<i>Guide</i> , pp 138, 150)		X			
○ heating ventilation and air conditioning (<i>Guide</i> , pp 139, 150-151)	X				
○ power and lighting (<i>Guide</i> , pp 141, 150)	X				
○ noise control (<i>Guide</i> , p 142)	X				
○ vibration control (<i>Guide</i> , p 142)	X				
○ environmental monitoring (<i>Guide</i> , p 143)	X				
• Water Quality:					
○ standards for acceptable quality are established (<i>Guide</i> , p 78)	X				
○ chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems (<i>Guide</i> , pp 78, 86) [must]	X				
• Life Support System:					
○ water source is based on appropriate controls and research requirements (<i>Guide</i> , p 79)	X				
○ biofilter is of sufficient size to process bioload (<i>Guide</i> , p 80) [must]					X
• Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:					
○ temperature and humidity (<i>Guide</i> , pp 43, 80-81)	X				
○ ventilation and air quality (<i>Guide</i> , pp 45, 81)	X				
○ illumination (<i>Guide</i> , pp 47, 81)	X				
○ noise and vibration (<i>Guide</i> , pp 49, 81)	X				
• Primary Enclosure:					
○ allows for normal physiological and behavioral needs (<i>Guide</i> , p 82)	X				
○ allows social interaction for social species (<i>Guide</i> , p 82)	X				
○ provides a balanced, stable environment (<i>Guide</i> , p 82)	X				
○ provides appropriate water quality and monitoring (<i>Guide</i> , p 82)	X				
○ allows access to food and waste removal (<i>Guide</i> , p 82)	X				
○ restricts escape and entrapment (<i>Guide</i> , p 82)	X				
○ allows undisturbed observation (<i>Guide</i> , p 82)	X				
○ constructed of nontoxic materials (<i>Guide</i> , p 82)	X				
○ prevents electrical hazards (<i>Guide</i> , p 82)	X				
○ space needs of species are evaluated by IACUC during program evaluations and facility inspections (<i>Guide</i> , p 83)	X				
• Environmental Enrichment, Social Housing, Behavioral and Social Management:					
○ enrichment elicits appropriate behaviors and is safe (<i>Guide</i> , p 83)	X				

NA = not applicable

NOTES:

Cagewash

Date: 11/21/2019

Location: GEMMD Wetlabs

	A*	M	S	C	NA
• Construction and Operation:					
○ dedicated central area for sanitizing cages and equipment is provided (<i>Guide</i> , p 143)	X				
○ cage-washing equipment meets need (<i>Guide</i> , p 143)					X
○ doors, windows, floors, drainage, walls, ceilings (<i>Guide</i> , pp 136-138)					X
○ convenient to animal areas/waste disposal (<i>Guide</i> , p 143)					X
○ ease of access (including door size) facilitates use (<i>Guide</i> , p 143)	X				
○ sufficient space for staging and maneuvering (<i>Guide</i> , p 143)	X				
○ safety precautions/clothing/equipment used for waste disposal/prewash/acid wash ((<i>Guide</i> , p 143)	X				
○ traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (<i>Guide</i> , p 143)					X
○ insulation and/or sound attenuation present as needed (<i>Guide</i> , p 143)					X
○ utilities are appropriate (<i>Guide</i> , p 143)	X				
○ ventilation meets heat and humidity load (<i>Guide</i> , p 143)	X				
○ safety features (e.g., SOPs, warning signs, eyewash stations) are in use (<i>Guide</i> , p 143)	X				
○ functioning safety devices to prevent entrapment in washer/sterilizers (<i>Guide</i> , p 143)					X
○ cage wash temperatures are monitored and records are available (<i>Guide</i> , p 73)					X
○ appropriate clean cage storage (<i>Guide</i> , p 141)	X				

* A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies

Date:

Location:

	A*	M	S	C	NA
<ul style="list-style-type: none"> General Considerations: <ul style="list-style-type: none"> labs used to house animals only when scientifically required and limited to minimum period necessary (<i>Guide</i>, p 134) drug storage, control, and expiration dates (<i>Guide</i>, pp 115, 122) sharps disposal (<i>Guide</i>, p 74) anesthetic monitoring (<i>Guide</i>, p 120) scavenging of anesthetic gases (<i>Guide</i>, p 21) safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place (<i>Guide</i>, p 19) carcass disposal (<i>Guide</i>, pp 73-74) Additional Concerns for Survival Surgery: (rodent and minor procedures only) <ul style="list-style-type: none"> rodent survival surgery clean and uncluttered, not used for anything else during surgery (<i>Guide</i>, p 144) records of peri-operative care (<i>Guide</i>, p 120) aseptic procedures (<i>Guide</i>, pp 118-119) autoclave monitoring procedures (<i>Guide</i>, pp 119, 145) storage of autoclaved materials (<i>Guide</i>, p 145) cold sterilization procedures are appropriate (<i>Guide</i>, p 119) Imaging/Whole Body Irradiation: NEW <ul style="list-style-type: none"> location of resource limits contamination risk (<i>Guide</i>, p 147) appropriate transportation methods are in place (<i>Guide</i>, p 147) gas anesthesia provision, scavenging and monitoring are appropriate (<i>Guide</i>, p 147) appropriate sensors and ventilation are provided for cryogen gases (<i>Guide</i>, p 147) must imaging console is located away from radiation source (<i>Guide</i>, p 147) Hazardous Agent Containment: NEW <ul style="list-style-type: none"> facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (<i>Guide</i>, p 148) must Behavioral Studies: NEW <ul style="list-style-type: none"> facility minimizes airborne transmission of noise and ground-borne transmission of vibration (<i>Guide</i>, p 149) floor coverings reduce sound transmission (<i>Guide</i>, p 149) testing equipment allows for surface disinfection (<i>Guide</i>, p 150) components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (<i>Guide</i>, p 150) housing areas are contiguous with testing areas when appropriate (<i>Guide</i>, p 150) 					X X X X X X X X X X X X X X X X X X X X X X X X X

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S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

NOTES:

III. Semiannual Program Review and Facility Inspection Report

Date: 11/21/2019

Members in Attendance: Jim Harvey, **Exemption 6**

Leslie Jarrell (via phone/Facetime) and

Exemption 6

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		Wetlab	MS222 and hCG need to be pharmaceutical grade. Replace with pharmaceutical grade.	Exemption 6 (CRL)		
M		T22/23	Wooden box step at T22/23 need to be repainted/sealed or the top replaced. Replace with plastic	Jim Harvey (JH)		
M		Wetlab	Columns supporting head boxes are showing serious rust. Will try to replace columns.	Exemption 6 (pH) (wetlab manager)		
WishList		Wetlab	Head Boxes in one section are crowded. Will try to uncrowd the boxes and use newer material to match the rest of the head boxes.			
WishList		Wetlab	Water Storage Tanks are due for cleaning. Need funds to have this done.			
WishList		Wetlab	Water testing. Need funds to test for heavy metals.			

* A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

✓ Check if repeat deficiency

IV. Endnotes

ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

ⁱⁱ Part 2 Subpart C - Research Facilities

- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

ⁱⁱⁱ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

^{iv} 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

^v 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

^{vi} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{vii} 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

^{viii} 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

^{ix} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{*} In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:
- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - “No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing...”

^{xi} 2.33(a)(1) - “In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.” [USDA requirement additional]

^{xii} 2.32(c) - “Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures.”

^{xiii} 2.32(c) - additional specifications include:

- “proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility”
- “methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility...”
- “utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act.” [USDA training specifications are more detailed than PHS Policy].

^{xiv} 2.31(d)(iv)(C) - “Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”

^{xv} Part 3 Subpart A 3.8 - “...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures...”

^{xvi} Part 3 Subpart D 3.81 - “...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates.”

^{xvii} Part 3 Subpart A 3.6(c)(1) - “Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows:

$(\text{length of dog in inches} + 6)^2 / 144 = \text{required floor space in square feet}.$ ”

- Part 3 Subpart D 3.80 (b) - “Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart.”

- In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.

Wavagunze H

I. Semiannual Program Review Checklistⁱ

Institutional Policies and Responsibilities: **ACESD**

Date: 12/12/2019

1. Animal Care and Use Program ^{NEW}

	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (Guide, p.1) [must]	X				
• IO has authority to allocate needed resources (Guide, p.13)	X				
• Resources necessary to manage program of veterinary care are provided (Guide, p.14) [must]	X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp.11, 15)	X				
• Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p.13)	X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (Guide, p.14) [must]	X				
• Inter-institutional collaborations are described in formal written agreements (Guide, p.15) QA Plans	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p.15) MOAs	X				

2. Disaster Planning and Emergency Preparedness ^{NEW}

	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (Guide, p.35, p.75) [must]	X				
• Plans include provisions for euthanasia (Guide, p.35) [must]	X				
• Plans include triage plans to meet institutional and investigators' needs (Guide, p.35)		X			
• Plans define actions to prevent animal injury or death due to HVAC or other failures (Guide, p.35)	X				
• Plans describe preservation of critical or irreplaceable animals (Guide, p.35)	X				
• Plans include essential personnel and their training (Guide, p.35)	X				
• Animal facility plans are approved by the institution and incorporated into overall response plan (Guide, p.35)	X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p.35)	X				

3. IACUC ^{NEW}

	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (Guide, p.25) [must]	X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p.26) [must]	X				
• Continuing IACUC oversight after initial protocol approval is in place (Guide, p.33)	X				

• IACUC evaluates the effectiveness of training programs (Guide, p 15)	X					
4. IACUC Protocol Review - Special Considerations	A*	M	S	C	NA	
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (Guide, p 27)	X					
• For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)						X
• For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28)						X
• Restraint devices are justified in the animal use protocols (Guide, p 29) [must]						X
• Alternatives to physical restraint are considered (Guide, p 29)						X
• Period of restraint is the minimum to meet scientific objectives (Guide, p 29)						X
• Training of animals to adapt to restraint is provided (Guide, p 29)						X
• Animals that fail to adapt are removed from study (Guide, p 29)						X
• Appropriate observation intervals of restrained animals are provided (Guide, p 29)						X
• Veterinary care is provided if lesions or illness result from restraint (Guide, p 30)						X
• [must]						X
• Explanations of purpose and duration of restraint are provided to study personnel (Guide, p 30)						X
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (Guide, p 30)						X
• Major versus minor surgical procedures are evaluated on a case-by-case basis (Guide, p 30)						X
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (Guide, p 30)						X
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (Guide, p 31)						X
• Body weights for food/fluid restricted animals are recorded at least weekly (Guide, p 31)						X
• Daily written records are maintained for food/fluid restricted animals (Guide, p 31)						X
• Pharmaceutical grade chemicals are used , when available, for animal-related procedures (Guide, p 31)	X					
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (Guide, p 31)	X					
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (Guide, p 32)	X					
• Disposition plans are considered for species removed from the wild (Guide, p 32)	X					
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (Guide, p 75)						X

5. IACUC Membership and Functions

- IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, [IV.A.3.](#))
- Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, [p 24](#))ⁱⁱ
- IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, [p 14](#))
- IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, [IV.B.](#))
- Conducts semiannual inspections of institutional animal facilities (PHS Policy, [IV.B.](#))
- IACUC organizationally reports to the Institutional Official (PHS Policy, [IV.A.1.b.](#))
- Methods for reporting and investigating animal welfare concerns are in place (*Guide*, [p 23](#)) **[must]**
- Reviews and investigates concerns about animal care and use at institutionⁱⁱⁱ (PHS Policy, [IV.B.](#))
- Procedures are in place for review, approval, and suspension of animal activities^{iv} (PHS Policy, [IV.B.](#))
- Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, [IV.B.](#))
- Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (*Guide*, [p 27-32](#)) QA Plans
- Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS^v (*Guide*, [p 30](#)) **[must]**

6. IACUC Training ^{NEW}

- All IACUC members should receive:
 - Formal orientation to institution's program (*Guide*, [p 17](#))
 - Training on legislation, regulations, guidelines, and policies (*Guide*, [p 17](#))
 - Training on how to inspect facilities and labs where animal use or housing occurs (*Guide*, [p 17](#))
 - Training on how to review protocols as well as evaluate the program (*Guide*, [p 17](#))
 - Ongoing training/education (*Guide*, [p 17](#))

7. IACUC Records and Reporting Requirements^{vi}

- Semiannual report to the IO (PHS Policy, [IV.B.](#))
 - Submitted to IO every 6 months
 - Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)
 - Includes minority IACUC views
 - Describes IACUC-approved departures from the *Guide* or PHS Policy and the reasons for each departure^{vii}

A* M S C NA

X

X

X

X

X

X

X

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X

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X

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X

A* M S C NA

X

X

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X

- X**

A

A

- A**

- Includes multiple contacts (*Guide*, [p 24](#)) **X**
 - Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (*Guide*, [p 24](#)) **X**
- * **A** = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

NOTES:

Veterinary Care

Date: 12/12/2019

1. Clinical Care and Management ^{NEW}

	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (<i>Guide, p 105</i>)	X				
• [must] Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (<i>Guide, p 106</i>)	X				
• Veterinarian provides oversight to surgery and perioperative care (<i>Guide, p 106</i>)					X
• Veterinary care program is appropriate for program requirements (<i>Guide, pp 113-114</i>)	X				
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide, p 114</i>)	X				
• Procedures to triage and prioritize incident reports are in place (<i>Guide, p 114</i>)	X				
• Procedures are in place to address:					
◦ Problems with experiments to determine course of treatment in consultation with investigator(<i>Guide, p 114</i>)	X				
◦ Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (<i>Guide, p 114</i>)	X				
◦ Veterinary review and oversight of medical and animal use records (<i>Guide, p 115</i>)					X
• Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide, p 114</i>) [must]				X	
• Procedures established for veterinary assessment, treatment, or euthanasia (<i>Guide, p 114</i>) [must]				X	
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (<i>Guide, p 114</i>) [must]	X				

2. Animal Procurement and Transportation/Preventive Medicine

	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (<i>Guide, p 106</i>) [must]	X				
• Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide, p 106</i>)	X				
• Procurement is linked to IACUC review and approval (<i>Guide, p 106</i>)	X				
• Random source dogs and cats are inspected for identification (<i>Guide, p 106</i>)					X
• Population status of wildlife species is considered prior to procurement (<i>Guide, p 106</i>)	X				
• Appropriate records are maintained on animal acquisition (<i>Guide, p 106</i>)	X				
• Animal vendors are evaluated to meet program needs and quality (<i>Guide, p 106</i>)					X
• Breeding colonies are based on need and managed to minimize numbers (<i>Guide, p 107</i>)	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (<i>Guide, p 107</i>) [must]	X				

- Transportation is planned to ensure safety, security and minimize risk (*Guide*, [p 107](#)) **X**
- Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (*Guide*, [pp 107-108](#)) **X**
- Appropriate loading and unloading facilities are available (*Guide*, [p 109](#)) **X**
- Environment at receiving site is appropriate (*Guide*, [p 109](#)) **X**
- Policies in place on separation by species, source, and health status (*Guide*, [pp 109, 111-112](#)) **X**
- Procedures in place for quarantine to include zoonoses prevention (*Guide*, [p 110](#)) **X**
- Quarantined animals from different shipments are handled separately or physically separated (*Guide*, [p 110](#)) **X**
- Procedures in place for stabilization/acclimation (*Guide*, [pp 110-111](#)) **X**
- Policies in place for isolation of sick animals (*Guide*, [p 112](#)) Just euthanized **X**
- Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (*Guide*, [p 112](#)) **X**
- Diagnostic resources are available for preventive health program (*Guide*, [p 112](#)) **X**

3. Surgery

- Surgical outcomes are assessed and corrective changes instituted (*Guide*, [p 115](#)) **X**
- Researchers have appropriate training to ensure good technique (*Guide*, [p 115](#)) **X**
- **[must]** Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide*, [p 116](#)) **X**
- Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide*, [p 116](#)) **X**
- Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide*, [pp 117-118](#)) **X**
- For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide*, [p 118](#)) **X**
- Aseptic technique is followed for survival surgical procedures (*Guide*, [pp 118-119](#)) **X**
- Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide*, [p 119](#)) **X**
- Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide*, [p 119](#)) **X**
- For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide*, [p 119](#)) **X**
- Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (*Guide*, [pp 119-120](#)) **X**

4. Pain, Distress, Anesthesia and Analgesia

- Guidelines for assessment and categorization of pain, distress and animal wellbeing **X**

- are provided during training (*Guide*, [p 121](#)) **X**
- Selection of analgesics and anesthetics is based on professional veterinary judgment (*Guide*, [p 121](#)) **X**
- Painful procedures are monitored to ensure appropriate analgesic management (*Guide*, [p 122](#)) **X**
- Nonpharmacologic control of pain is considered as an element of postprocedural care (*Guide*, [p 122](#)) **X**
- Procedures are in place to assure antinociception before surgery begins (*Guide*, [p 122](#)) **X**
- [must]**
- Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (*Guide*, [p 122](#)) **X**
- Special precautions for the use of paralytics are in place to ensure anesthesia^{xiv} (*Guide*, [p 123](#)) **X**

5. Euthanasia

- Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide*, [p 123](#)) **A* M S C NA**
- Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide*, [pp 123-124](#)) **X**
- Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide*, [p 124](#)) **X**
- Procedures and training are in place to ensure death is confirmed (*Guide*, [p 124](#)) **X**
- [must]** In progress as well

6. Drug Storage and Control ^{NEW}

- Program complies with federal regulations for human and veterinary drugs(*Guide*, [p 115](#)) **[must]** **A* M S C NA**
- Drug records and storage procedures are reviewed during facility inspections (*Guide*, [p 115](#)) **X**
- Procedures are in place to ensure analgesics and anesthetics are used within expiration date (*Guide*, [p 122](#)) **[must]** **X**
- Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide*, [p 122](#)) **X**

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NA = not applicable

NOTES:

- | | |
|--|---|
| <ul style="list-style-type: none"> noise and vibration (Guide, pp 49, 81) | X |
| <ul style="list-style-type: none"> Primary Enclosure: <ul style="list-style-type: none"> allows for normal physiological and behavioral needs (Guide, p 82) allows social interaction for social species (Guide, p 82) provides a balanced, stable environment (Guide, p 82) provides appropriate water quality and monitoring (Guide, p 82) allows access to food and waste removal (Guide, p 82) restricts escape and entrapment (Guide, p 82) allows undisturbed observation (Guide, p 82) constructed of nontoxic materials (Guide, p 82) prevents electrical hazards (Guide, p 82) space needs of species are evaluated by IACUC during program evaluations and facility inspections (Guide, p 83) | X |
| <ul style="list-style-type: none"> Environmental Enrichment, Social Housing, Behavioral and Social Management: <ul style="list-style-type: none"> enrichment elicits appropriate behaviors and is safe (Guide, p 83) semi-aquatic reptiles are provided terrestrial areas (Guide, p 83) handling is kept to a minimum and appropriate techniques are in place at facility or protocol level (Guide, p 84) nets are cleaned, disinfected and managed to avoid contamination of systems (Guide, p 84) | X |
| <ul style="list-style-type: none"> Food: <ul style="list-style-type: none"> storage to prevent contamination, preserve nutrients and prevent pests (Guide, p 84) delivery ensures access to all , minimizing aggression and nutrient loss (Guide, p 84) storage times are based on manufacturer recommendations or accepted practice (Guide, p 84) a nutritionally complete diet is provided (Guide, p 84) | X |
| <ul style="list-style-type: none"> Substrate: <ul style="list-style-type: none"> amount, type and presentation of substrate is appropriate for the system and the species (Guide, p 85) | X |
| <ul style="list-style-type: none"> Sanitation, Cleaning and Disinfection <ul style="list-style-type: none"> frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (Guide, p 86) cleaning and disinfection of macroenvironment (Guide, p 86) | X |
| <ul style="list-style-type: none"> Waste Disposal: <ul style="list-style-type: none"> procedures for collection (Guide, pp 73-74) | X |

- hazardous wastes are rendered safe before removal from facility (*Guide*, [pp 73-74](#)) **[must]** **X**
 - animal carcasses (*Guide*, [pp 73-74](#)) **X**
 - **Pest Control:**
 - regularly scheduled (*Guide*, [p 74](#)) **X**
 - documented program including control of pests and insecticide use (*Guide*, [p 74](#)) **X**
 - **Emergency, Weekend, and Holiday Animal Care:**
 - care provided by qualified personnel every day (*Guide*, [pp 74, 87](#)) **X**
 - provision for accessible contact information (*Guide*, [pp 74, 87](#)) **X**
 - emergency response plans in place to address major system failures (*Guide*, [87](#)) **X**
 - veterinary care available after hours, weekends, and holidays (*Guide*, [pp 74, 114](#)) **X**
 - **[must] Identification:**
 - cage/tank cards contain required information (*Guide*, [pp 75, 87](#)) **X**
 - genotype information included and standardized nomenclature used when applicable (*Guide*, [pp 75, 87](#)) **X**
 - **Recordkeeping:**
 - water quality parameters and frequency of testing recorded (*Guide*, [p 88](#)) **X**
 - records kept on feeding, nonexpired food supplies, live cultures (*Guide*, [p 88](#)) **X**
 - **Storage:**
 - adequate space for equipment, supplies, food, substrate and refuse (*Guide*, [p 141](#)) **X**
 - substrate protected from contamination (*Guide*, [p 141](#)) **X**
 - food in vermin-free, temperature and humidity controlled area and protected from contamination (*Guide*, [p 141](#)) **X**
 - refuse storage is separate (*Guide*, [p 141](#)) **X**
 - carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (*Guide*, [p 141](#)) **X**
 - **Personnel:**
 - adequate space for locker rooms, administration and training (*Guide*, [p 135](#)) **X**
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NA = not applicable

NOTES:

Cagewash

Date: 12/12/2019

Location: ACESD

	A*	M	S	C	NA
• Construction and Operation: Cage wash meets their needs					
◦ dedicated central area for sanitizing cages and equipment is provided (<i>Guide, p 143</i>)	X				
◦ cage-washing equipment meets need (<i>Guide, p 143</i>)	X				
◦ doors, windows, floors, drainage, walls, ceilings (<i>Guide, pp 136-138</i>)					X
◦ convenient to animal areas/waste disposal (<i>Guide, p 143</i>)	X				
◦ ease of access (including door size) facilitates use (<i>Guide, p 143</i>)	X				
◦ sufficient space for staging and maneuvering (<i>Guide, p 143</i>)	X				
◦ safety precautions/clothing/equipment used for waste disposal/prewash/acid wash ((<i>Guide, p 143</i>)	X				
◦ traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (<i>Guide, p 143</i>)	X				
◦ insulation and/or sound attenuation present as needed (<i>Guide, p 143</i>)					X
◦ utilities are appropriate (<i>Guide, p 143</i>)	X				
◦ ventilation meets heat and humidity load (<i>Guide, p 143</i>)	X				
◦ safety features (e.g., SOPs, warning signs, eyewash stations) are in use (<i>Guide, p 143</i>)	X				
◦ functioning safety devices to prevent entrapment in washer/sterilizers (<i>Guide, p 143</i>)	X				
◦ cage wash temperatures are monitored and records are available (<i>Guide, p 73</i>)	X				
◦ appropriate clean cage storage (<i>Guide, p 141</i>)	X				

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C = change in program (PHS Policy [IV.A.1.a-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

II. Semiannual Program Review and Facility Inspection Report

Date: 12/12/2019

Members in Attendance:

Exemption 6 Exemption 6

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M		Wetlab	Emergency Eye Wash needs 18 inches of egress. Move chair to another location.			12/12/2019
M		Wetlab-G15	Rusty scrapers. Replace rusty scrapers with new scrapers.			
M		Wetlab-Tank 21A & another tank	Rusty clipboards (2). Replace rusty clipboards with new clipboards.			
M		Wetlab	Ambient salinity tubings are dirty. Replace with new tubing. In progress as newer type of replacement tubing is on order			
M		Wetlab	Emergency Eye Wash needs 18 inches of egress. Move boot rack to another location.			12/12/2019

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S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

✓ Check if repeat deficiency

III. Endnotes

ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

ⁱⁱ Part 2 Subpart C - Research Facilities

- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

ⁱⁱⁱ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

^{iv} 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

^v 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

^{vi} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{vii} 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

^{viii} 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

^{ix} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:
- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - “No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing...”

^{xi} 2.33(a)(1) - “In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.” [USDA requirement additional]

^{xii} 2.32(c) - “Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures.”

^{xiii} 2.32(c) - additional specifications include:

- “proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility”
- “methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility...”
- “utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act.” [USDA training specifications are more detailed than PHS Policy].

^{xiv} 2.31(d)(iv)(C) - “Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”